

Application No. 10/795,837  
Amendment After Final dated June 24, 2008  
Reply to Final Office Action of January 24, 2008

**REMARKS/ARGUMENTS**

Applicants submit, contemporaneously herewith, a Request for Continued Examination pursuant to 37 C.F.R. §1.114.

Claims 1-21 are pending. Claims 19-21 have been withdrawn. Claim 18 has been allowed. Claims 1-5 and 17 have been rejected. Claims 6-16 have been objected to.

**Claim Rejections – 35 U.S.C. § 103(a)**

Claims 1-5 and 17 are rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent Application Publication No. 2003/0220689 to Ritland et al ("Ritland '689").

Ritland '689 discloses a device for positioning implants, shown in Fig. 1, including inner part 10 and outer part 20. Inner part 10 includes guide engagement section 12 that is guided positioned in and guided by guide section 22 of outer part 20. Guide section 22 of outer part 20 forms a rail for providing longitudinal direction to guide engagement section 12. Longitudinal drill hole or passage 14 extends through guide engagement section 12 and allows instruments, such as mills or threading means, to pass therethrough.

Applicants respectfully submit that independent Claim 1 is not obvious over Ritland '689, as Ritland '689 fails to disclose or suggest each and every limitation of independent Claim 1. Specifically, independent Claim 1 calls for a navigated stemmed implant inserter for use with a stemmed orthopaedic implant defining a longitudinal stem axis and a surgical navigation system, the inserter including, *inter alia*, a stem engaging member engageable with the stemmed orthopaedic implant in rigid relative arrangement and an elongated rod translatable along a body of the navigated stemmed implant inserter, wherein the elongate rod is translated along a longitudinal axis substantially parallel with the longitudinal stem axis to lockingly engage the stem engaging member with the stemmed orthopaedic implant.

In forming the rejection, the Examiner indicates, and Applicants respectfully agree, that Ritland '689 does not explicitly recite any means for the adjustability of the implant inserter or the type of implant inserter called for in amended independent Claim 1. Thus, in forming the rejection, the Examiner relies on the ability of a person of ordinary skill in the art to transform

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the device of Ritland '689 into the claimed invention. In formulating a rejection under 35 U.S.C. § 103(a), the Examiner must identify in an Office Action a rational basis for why a person of ordinary skill in the art would have combined or modified the prior art elements in the manner claimed. *See KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350 (U.S. Apr. 30, 2007) (a patent examiner must provide "an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate this review, this analysis should be made explicit."); *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (cited with approval in *KSR*) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.")

Thus, the rational basis for why a person of ordinary skill in the art would have modified the device of Ritland '689 to provide a stem engaging member and an elongate rod translatable along the body of a navigated stemmed implant inserter, wherein the elongate rod is translated along the longitudinal axis substantially parallel to the longitudinal stem axis *to lockingly engage a stem engaging member with the stemmed orthopaedic implant* is indicated by the Examiner to "have amounted merely to a substitution of functionally equivalent tools and implant structures known in the art." Office Action dated January 24, 2008, page 2. However, the Examiner fails to identify any known tool that performs the same function as the claimed device or that even operates in a similar manner. Instead, Applicants are left with the Examiner's conclusory statements that it would be obvious to modify the device of Ritland '689, i.e., a device that facilitates the drilling of holes into pedicles of vertebra, to arrive at the claimed invention. However, "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." MPEP §2142, 8<sup>th</sup> ed. (citing *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)); *see also KSR v. Teleflex*, 550 U.S. at \_\_\_, 82 USPQ2d at 1396.

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For at least the foregoing reasons, Applicants respectfully submit that independent Claim 1, as well as Claims 2-5 and 17, which depend therefrom, are not obvious over Ritland '689.

**Allowable Subject Matter**

Applicants respectfully thank the Examiner for the allowance of Claim 18 and the indicated allowability of Claims 6-16.

In the event Applicants have overlooked the need for an additional extension of time, payment of fee, or additional payment of fee, Applicants hereby petition therefor and authorize that any charges be made to Deposit Account No. 02-0385, Baker & Daniels.

Should the Examiner have any further questions regarding any of the foregoing, he is respectfully invited to telephone the undersigned at 260-424-8000.

Respectfully submitted,



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Signature

June 24, 2008

Date